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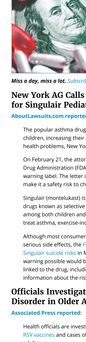
EXECUTIVE SUMMARY

New York AG Calls for More Stringent Warnings for Singulair Pediatric Suicide Risks + More

The Defender's Big Pharma Watch is news and information items related to pharmaceutical companies and their products, including vaccines, drugs, and medical devices and treatments. The views expressed in the below excerpts from other news sources do not necessarily reflect the views of The Defender. Our goal is to provide readers with breaking news that affects human health and the environment.

By The Defender Staff



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New York AG Calls for More Stringent Warnings for Singulair Pediatric Suicide Risks

AboutLawsuits.com reported:

The popular asthma drug Singulair poses a serious mental health threat to children, increasing their risk of suicide, aggression, and other mental health problems, New York Attorney General Letitia James warns.

On February 21, the attorney general sent a letter to the U.S. Food and Drug Administration (FDA) calling for changes to be made to Singulair's warning label. The letter indicates that Singulair's mental health side effects make it a safety risk to children in the U.S.

Singulair (montelukast) is an asthma medication that belongs to a class of drugs known as selective leukotriene receptor antagonists. It is widely used among both children and adults, involving a daily pill taken every once a day to treat asthma, exercise-induced asthma and seasonal allergies.

Although most consumers believe the medication is safe and carries few serious side effects, the FDA issued a drug safety communication about the Singulair suicide risks in March 2020, announcing that the strongest label warning possible would be added regarding mental health side effects linked to the drug, including a prominent "black box" containing information about the risk of suicidal thoughts and behavior.

Officials Investigate Rare Nervous System Disorder in Older Adults Who Got RSV Vaccine

Associated Press reported:

Health officials are investigating whether there's a link between two new RSV vaccines and cases of a rare nervous system disorder in older U.S. adults.

The inquiry is based on fewer than two dozen cases seen among more than 9.5 million vaccine recipients, health officials said Thursday. And the available information is too limited to establish whether the shots caused the illnesses, they added.

But the numbers are higher than expected and officials are gathering more information to determine if the vaccines are causing the problem. The data was presented at a meeting of an expert panel that provides vaccine policy advice to the Centers for Disease Control and Prevention.

Officials said they were investigating more than 20 cases of Guillain-Barré syndrome, an rare illness in which a person's immune system damages nerve cells, causing muscle weakness and paralysis. An estimated 3,000 to 6,000 people develop GBS in the U.S. each year, and it's more commonly seen in older people, according to the CDC.

Last year, the CDC signed off on a recommendation made by the advisory panel, aimed at Americans age 60 and older. It was for a single dose of RSV vaccine. There were two options, one made by Pfizer and the other by GSK.

Changes in Gay Men's Behaviors, Not Vaccine, Halted Mpox Outbreak

U.S. News & World Report reported:

New research finds the 2022 mpox outbreak among gay and bisexual men began to slow down after just a few months — even though just 8% of high-risk people had received the mpox vaccine.

That suggests that it was changes in gay and bisexual men's sexual behaviors, not the vaccine, that caused the outbreak to subside, researchers concluded.

"Once the mpox epidemic was recognized, behavioral modification in the men-who-have-sex-with-men community resulted in a sharp decline in [the rate of transmission] in North America ahead of vaccination rollout in the U.S.," concluded a team led by Miguel Paredes, an epidemiologist at the Fred Hutchinson Cancer Center in Seattle.

Paredes' team published its findings Feb. 29 in the journal Cell.

The Vaccine Doctors Want Every Single Person Over 50 to Get ASAP

Parade reported:

If your 50th birthday is on the horizon, there's one vaccine doctors are begging their patients to get: the shingles vaccine. "I would definitely recommend it," says Dr. Kenneth Kondjia, MD, a geriatrician and internal medicine physician with the Cleveland Clinic's Center for Geriatric Medicine.

Yes, your doctor still wants you to get a seasonal flu vaccine and COVID booster too. But those are vaccines that you'll need to get every year. The shingles vaccine is actually a two-shot series, but you only have to complete the series once. Then you should be good to go. Read on for my information on the shingles vaccine, and why it's so important to get it.

"Everyone over age 50 should get the shingles vaccine, regardless of whether or not you've had shingles in the past, whether you've had the live vaccine, or whether you remember having chickenpox in the past," says Dr. Tan. "Everyone needs to get the shingles vaccine."

Mental Health Crisis Fuels the Post-Pandemic Rise in Medication Use

USA TODAY reported:

A USA TODAY analysis of Medicaid data for the 60 most used psychiatric drugs showed a growing number of people sought treatment of health treatment and medication during the pandemic as it pushed people into isolation and dismantled support systems.

The analysis also revealed a lingering effect of the pandemic: Mental health-related prescriptions rose further in 2022, up 12% from 2019, outpacing the less than 1% growth in overall prescriptions. That includes prescriptions for generic Zoloft, the most common antidepressant medication, which rose 17% over the same period.

More than half of these drugs saw an increase in prescriptions since 2019, and the steepest increase was among ADHD drugs: Concerta and generic Adderall.

Obesity Drugs Won't Fix a Billion-Person Problem, WHO Warns

Bloomberg reported:

Effective, popular obesity medications won't be enough to solve a worldwide problem that now affects more than 1 billion people, World Health Organization officials warned.

Obesity has quadrupled among children and teens and more than doubled among adults since 1990, with about one in every eight people in the world living with the condition, the health agency said Thursday in the first global public analysis of the condition since 2017.

New obesity drugs such as Novo Nordisk A/S's Wegovy and Eli Lilly & Co.'s Zepbound could be an $80 billion market by 2030. However, they will probably contribute to the growing problem of inequality around weight-loss treatment, said Majid Ezzati, a professor of global environmental health at Imperial College London and the senior author of the study.

"These drugs are definitely an important tool, but they should not be seen as a solution to the problem," said Francesco Branca, director of the Department of Nutrition and Food Safety at WHO, who was a co-author of the study. "The solution is still the transformation of food systems and the environment."

Gardasil HPV Vaccine Side Effects Led to Rheumatoid Arthritis Diagnosis, Lawsuit Alleges

AboutLawsuits.com reported:

Merck faces a new product liability lawsuit brought by an Ohio woman, who indicates she developed rheumatoid arthritis from Gardasil HPV vaccine side effects, indicating that injections received when she was 22 years old have left her unable to continue her career and activities that a normal young person would enjoy.

The complaint was filed by Jessica Brown on February 22 in the U.S. District Court for the Western District of North Carolina, indicating that she experienced complications after receiving three doses of the HPV vaccine.

This case now joins a growing number Gardasil lawsuits being pursued against the manufacturer, alleging that Merck has withheld information about permanent and life-changing autoimmune side effects linked to the HPV vaccination from users, families and the medical community for years.

Endo Agrees to $4,65 Million Bankruptcy Deal With Federal Government, Inks 2 Opioid Settlements

Fierce Pharma reported:

As Endo looks to emerge from bankruptcy, the company has agreed to fork over up to $464.9 million to the federal government, which had been investigating its marketing of opioid painkiller Opana ER.

On Thursday, the U.S. Department of Justice (DOJ) said Endo has reached settlements in civil and criminal cases over its prior marketing of Opana ER. In addition, Endo inked a bankruptcy settlement worth up to $464.9 million, which essentially supersedes the civil and criminal deals for financial purposes.

Here Are the Cancer Drugs Pfizer Thinks Could Reignite Investors' Interest

STAT News reported:

Pfizer spent more than four hours Thursday laying out its oncology program to investors. But the company also spent some time talking about the effects of the Inflation Reduction Act on its pipeline.

The drug giant, which is facing investor dissatisfaction after a year in which its stock dropped 44%, said it would be focusing on drugs that are based on proteins, not small molecule pills as it has traditionally developed. (Pfizer's current best-seller in oncology, Ibrance for breast cancer, is a small molecule pill.) It said the mix of small molecule drugs in its cancer portfolio will drop from 54% last year to 35% in 2030.

That matters because small molecules are more vulnerable to generic competition and the Medicare price negotiation introduced by the IRA. Sunnet Varma, the commercial president of Pfizer's oncology unit, said: "This planned shift to biologics is expected to support the accelerated growth in both the top and bottom line," referring to the revenue and profit lines of a balance sheet.

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Best Newest Oldest

Lynn Hawkins
2 months ago
Why the push for the Shingles vaccine? Everyone I know of that has gotten the shingles vaccine has gotten shingles, and NOT a light case! My cousin, who got the 2 shot vaccine for shingles has had shingles FOUR TIMES now and each time it is bad enough for her to be hospitalized!!! She never had shingles before the shots! NO THANKS! I'll just "SAY NO!" to this jab like I do the rest!
Reply

Jenelle
2 months ago
Oh boy, so many reports here that have me angry.
Common sense lesson 101: anything that suppresses your immune system is HARMFUL & will eventually in continuum cause damage somewhere in the body. Lesson over.
Reply

Virgil Reginal
2 months ago
Re: "The Vaccine Doctors Want Every Single Person Over 50 to Get ASAP."
CRAZY FOR STUPID !
Reply

Peter van der Sluijs
2 months ago
YES! This is only for the extra stupid, brainless individuals and the positive bank accounts of the billionaires
Reply

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